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APPLICATION NUMBER: ***60/551,976***
FILING DATE: ***March 11, 2004***

AU/05/346

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
SATYAJIT ROHAN	JAYASINGHE	310 EAST 24th STREET APT #2L NEW YORK NY 10010

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

PROSTHETIC MITRAL VALVE AND ANCHORING DEVICE FOR PER CUTANEOUS DEPLOYME

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS (*check all that apply*)

☑ Specification *Number of Pages* 9
☑ Drawing(s) *Number of Sheets* 5
☑ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number _____
☐ Other (specify) _____

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Respectfully submitted,

SIGNATURE _____

TYPED or PRINTED NAME SR JAYASINGHE

TELEPHONE 917 206 6334

Date 3/3/2004

REGISTRATION NO. _____ *(if appropriate)*

Docket Number: _____

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Effective 10/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 80.00

Complete if Known	
Application Number	
Filing Date	3-3-2004
First Named Inventor	SR JAYASINGHE
Examiner Name	
Art Unit	
Attorney Docket No.	

METHOD OF PAYMENT *(check all that apply)*

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80

SUBTOTAL (1) ($) 80

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims	-20** =		X	=	
Independent Claims	- 3** =		X	=	
Multiple Dependent				=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

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3. ADDITIONAL FEES

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1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

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SUBMITTED BY

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Signature				Date 3-3-04

(Complete *(if applicable)*)

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I hereby claim small entity status for this invention

PROSTHETIC MITRAL HEART VALVE AND ANCHORING DEVICE FOR PER CUTANEOUS DEPLOYMENT

SR Jayasinghe
Inventor
3-4-04

Application Data Sheet

Application Information:

Application Type: Regular

Subject Matter: Utility

Suggested Classification: 623

Suggested Group Art Unit:

CD – ROM or DR-R?: None

Title: Prosthetic Mitral Valve and Anchoring Device for Percutaneous Deployment

Attorney Docket Number: None

Request for Early Publication: No

Request for Non-Publication: No

Suggested Drawing Figure:

Total Drawing Sheets: 4

Small Entity: Yes

Petition Included: No

Secrecy Order in Parent Appl.?:No

Applicant Information

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Status: Full Capacity

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Specification:

Prosthetic mitral heart valve and anchoring device for percutaneous deployment

An artificial mitral heart valve comprises a flexible/expandable firm, cylindrical stent member having a first ring shape with two leaflets one longer placed in the outer aspect and one shorter placed in the inner aspect. The total construct of the stent apparatus and the valve apparatus that is structurally a single unit is made of malleable or super-elastic but adequately rigid metal alloy (possibly nitinol). The detailed structure of the valva base which is a ring or a cylinder is made of woven metal alloy wire. The valve leaflets may be made of woven metal alloy wire (if so made to be contiguous with the architecture of the stent member) or animal or human connective tissue material. The whole apparatus including the stent member and leaflets, is self expandable (and partly balloon expandable if necessary) into its final ring and leaflet shape. The valve comprises of two leaflets attached to the peripheral rim and movable on the attachment hinge point in a manner that facilitates blood flow only in one direction-from the atrial side to the ventricular side. The valve leaflets lock in the direction of the atrium (retrograde) and open in the direction of the ventricle when deployed therefore functions as a one way valve.
Prior to deployment the total valve apparatus remains collapsed and housed within a delivery sheath or catheter.

Inventors: **S R Jayasinghe (New York NY)**
Assignee: **SR Jayasinghe (New York NY)**
Appl. No.:
Filed:

Current U.S. Class:
Intern'l Class:
Field of Search:

References Cited

U.S. Patent Documents

4,218,783	Aug., 1980	Reul.
6,210,432	Apr., 2001	Solem.
6,485,489	Nov., 2002	Tierstein.
6,569,198	Mar., 2003	Wilson.
6,537,314	Mar., 2003	Langberg.

Claims

What is claimed:

1. An artificial cardiac-mitral valve comprising

-self-expanding, malleable rigid/ super-elastic ring member circular or short cylindrical in shape, with adequate radial strength and made out of metal alloy.

- a valve member comprising one-way valve mounted on and fixed to the ring member (base)/ leaflets made of woven metal wire or fabric or tissue or a combination thereof attached to the ring base at hinge points (one or more per leaflet). Leaflets are two in number - one long leaflet(outer – ventricular side) and one shorter leaflet (inner – atrial side), leaflets moving in a manner that may create a one way valve.

- an anchoring plate attached to the atrial aspect of the valve apparatus via wires/strings of suitable length. The anchoring plate is anchored or placed on the inter atrial septum in the right atrial side thus firmly anchoring the valve apparatus to the native mitral annulus /to the mitral inflow area of the left ventricle by the multiple of taught strings.

The whole apparatus is collapsible to be stored in a housing / delivery catheter/ sheath. The apparatus is expandable to its final shape and structure when released from the housing/delivery sheath due to its super-elastic nature. The diameter of the ring member is slightly larger than that of the human mitral valve ring/ orifice/ annulus. Upon expansion it may take the configuration of or confirm to the shape of the mitral annulus thus ensuring firm attachment of the cylindrical/ circular valve ring member to the now crushed/ compressed under, native mitral valve apparatus and the annulus. On the outer aspect of the ring apparatus are small fine hooks/ spike- like structures/barbs for the attachment of the apparatus to the cardiac surface/ tissue of the native valve annulus, firmly upon deployment.

A method of implanting an artificial heart valve, which method comprises of initial approach to the right heart and approach to the mitral valve via trans-septal approach. First the long guide wire (0.035 or 0.064 size) to be introduced to the left ventricle in the above-mentioned manner. The wire edge to be snared in the left ventricle by a snare introduced via the arterial approach (retrograde) from left or right femoral artery, aorta and aortic valve. The guide wire introduced via the right heart is then surfaced from the left or right femoral artery and steadied outside of the patient's body. But the deployment of the valve could also be done through venepuncture alone, without arterial puncture, provided that the delivery mechanism is stable and optimal.

A guiding catheter (with a more rigid introducer sheath within it) is introduced (larger than or of the size of 8 F diameter/ larger than the now compressed in the storage form, the valve apparatus and the anchoring disc) from the femoral vein (right or left) along the pre-positioned wire (as mentioned above) and placed in the left ventricle.

Upon positioning of the distal end of the introducer catheter in the left ventricle as described above, the introducer to be removed and the lumen to be flushed with liquid to ensure no air is in the system.

Then the collapsed valve apparatus and the anchoring disc (pre-collapsed and housed in a sheath or collapsed de novo at the site) are advanced along the introducer sheath to the left ventricle.

All above steps to be performed under the guidance of a radiological image intensifier. Once the distal tip of the valve apparatus appears at the distal end of the introducer sheath (now positioned in the left ventricle) the valve apparatus (made of the ring/rim base member and the movable leaflets) is released and the base is firmly placed and fixed against the native valve annulus by exerting traction (pull) on the valve delivery system. The leaflets of the prosthesis face the left ventricular cavity and open during ventricular diastole and close during systole. Then the delivery sheath/ catheter is pulled back in a controlled manner to the right atrial side across the septum and all the while traction is maintained on the valve now held against the native mitral apparatus annulus and other tissues of its structure. In the right atrium the anchoring disc is released with the wires connecting the disc member to the valve rim being maintained taught thus anchoring the valve apparatus firmly and in a very stable and stationary manner in its place as described above.

Upon expansion of the valve apparatus it will be deployed by crushing the native valve leaflets and the cylindrical rim (stent) apparatus assuming the configuration of the inner aspect of the native valve rim. Firm expansion of a balloon, only if necessary, ensures firm and tight deployment of the prosthetic valve apparatus. (The alternative design is to construct the stent segment of the prosthetic valve to be wholly balloon expandable thus ensuring precise deployment and eliminating any possibility of mal-apposition or valve dislodgement prior to complete deployment of it with the balloon inflation)

Field of the invention

This invention relates to the placement of the mitral valve in a percutaneous manner thus replacing the regurgitant and diseased native mitral valve without the removal of the same. The native valve is to be crushed under the cylindrical stent of the deployed prosthetic valve. This is intended initially to be a minimally invasive therapeutic modality for end stage congestive cardiac failure exacerbated by or associated with severe mitral regurgitation in the patients not responding well to medical therapy and not fit for surgery (not exclusively so). This description fits millions of patients in the US and around the world. As life expectancy and ability to keep more patients with congestive cardiac failure alive, the population that would benefit from valve replacement by this catheter-based technique is projected to grow by very large proportions.

Background of the invention

A catheter based mitral valve replacement would be an optimal strategy for the patient with multiple co-morbidities and severe congestive cardiac failure who is a poor open-heart surgical

risk. Other catheter-based techniques at reducing the severity of the mitral regurgitation that is short of total valve replacement may be at times inadequate in most patients to bring about a lasting clinical improvement of symptoms. Catheter based valve replacement technology has made significant headway in the realms of aortic valve replacement. However due to multiple of reasons this progress has not been seen in the realms of catheter based technology for the mitral valve repair and replacement. One major challenge with the mitral valve is its anatomy and the anatomy of the mitral valve annulus in the dilated heart. The other challenge is firm positioning or placement of the delivered prosthetic valve apparatus in the intended location (where the native mitral valve is). The anatomy thereof is very distorted and often of unpredictable and non-uniform in shape and geometry. This makes it practically impossible to design a catheter based mitral valve prosthesis that would fit the annulus in a satisfactory manner for safe, stable and meticulous deployment. In the current invention this challenge has been surmounted by using a woven super-elastic metal construct and an anchoring mechanism by which the deployed valve apparatus is firmly anchored to where the native mitral valve is located and to the interatrial septum.

Catheter based percutaneous valve replacement is currently studied as treatment for defective aortic valves. Mitral incompetence is as common as or even more common than, aortic valvular disease but there is no catheter-based technique developed to replace or supplant the mitral valve. Mitral valvotomy using a compliant balloon is a widely practiced method of treating mitral stenosis. However this technology has not been developed to treat mitral incompetence but the possibilities exist. The major challenge of mitral valve replacement or reconstruction is the anatomical non-uniformity of the mitral annulus and firm anchoring of the deployed prosthesis. Due to this reason a pre constructed mitral valve apparatus may be difficult to be aligned well for deployment. In the current invention this challenge is effectively and efficaciously circumvented by using the malleable super-elastic metal, woven-wire construct and anchoring the deployed device to the interatrial septum. In addition the current design does not necessitate the removal of the diseased mitral valve however it may be desirable at times. It is to be crushed in to the cardiac architecture by the expanding balloon and the deployed stent apparatus of the valve.

Initially this therapy is meant to be for the patients with dilated left ventricle associated with severe congestive cardiac failure and poor operative risk for mitral valve surgery. However as the technical refinement and experience advances this may be able to be applied to all patients with mitral incompetence.

The catheter based mitral valve therapeutic techniques described hitherto have all advocated the removal of the native valve apparatus as the first step. This is a technically extremely challenging task associated with the potentially fatal complication of profound mitral regurgitation that may not be addressed by the complete procedure subsequently. The interim with no effective mitral valve present may lead to overwhelming hemodynamic instability that may not be tolerated by the already compromised left ventricle and overwhelming pulmonary edema may result rapidly. The current invention precludes such necessity and the patient may remain stable at the preoperative level till the prosthetic valve is deployed.

Endovascular procedures have significant benefits both from the standpoint of procedural morbidity, convenience as well as cost. Such are performed percutaneously via arterial and venous approach to the heart. Procedure can be performed under fluoroscopy, trans-esophageal echocardiography, intracardiac echocardiography and transthoracic echocardiography.

Numerous techniques that are catheter-based and/or minimally invasive for the replacement of the cardiac valves have been developed and published in the scientific literature. Following is a selected list of publications to this effect –

1. H. R. Andersen et al., entitled "Transluminal Implantation of Artificial Heart Valves", European Heart Journal (1992), Vol. 13, pp. 704-708;

2. L. L. Knudsen et al., entitled "Catheter-Implanted Prosthetic Heart Valves", The International Journal of Artificial Organs, Vol. 16, No. 5 (1993), pp. 253-262;

3. Prosthetic Aortic Valve for Trans-Catheter Placement", Radiology (1992), Vol. 183, pp. 151-154.

Patented endovascular valve devices-

1. Stevens, U.S. Pat. No. 5,370,685.

Each of above experimental and clinical models and concepts have inherent methodological and outcome problems that include stable and secure positioning and securing of the valve apparatus, problems of safe and effective delivery and apposition to the native architecture, and possible persistent valve insufficiency once placed.

Objectives of the Invention

The primary objective of the current invention is to provide a prosthetic apparatus and a means by which a defective and severely incompetent mitral valve could be replaced or supplanted with the prosthesis with or without the removal of the native valve apparatus in patients with severe mitral regurgitation with or without severe congestive cardiac failure.

Prosthetic valve is made of a combined structure that has a stent segment and two mobile leaflets all made of woven super-elastic metal alloy with or without integrated connective tissue construct. Tissue material can be used for the construction of valve leaflets but not necessarily.

The means by which it is deployed involves a per-cutaneous technique that involves access to the left heart via femoral venous approach and trans-septal puncture. The delivery mechanism may be but not necessarily, further stabilized by the snaring, procurement and stabilization by resurfacing of the guiding wire retrogradely via the left ventricle, aortic valve and the femoral

artery.
It is also an object of the present invention to provide a heart valve that can be relatively easily placed and secured in position.

The prosthetic valve may be potentially thrombogenic and may necessitate continues therapy with anti-platelet agent or coumadin or a derivative thereof. But incorporation of biological material or less thrombogenic material to the construction of valve leaflets may obviate such requirement.

The percutaneously placed valve may replace the native valve by sitting over it and thus obviating the necessity of the removal of the defective valve apparatus.

It is likewise an object of the present invention to provide a method and device for implanting an artificial heart valve using minimally invasive endovascular techniques with access of both the right and the left sides of the heart.

This invention is expected to preclude the removal of the defective native mitral valve.

It is additionally a further object of the present invention to provide for the minimally invasive or endovascular placement of heart valves while preventing embolization.

These and other objects of the invention will become more apparent in the discussion below.

Summary of the invention –

The invention herein encompasses methods and devices for the endovascular replacement or supplantation of diseased or defective mitral valve. The invention includes a prosthetic mitral valve which is implanted per-cutaneously and transluminally. The heart valve comprises a stent member and a valve means. The stent member is self-expanding and has within it valve means that permits flow in only one direction from the atrial side to the ventricular side. The stent member has barbs/short sharp hooks that anchor the expanded stent member at the level of the native mitral valve/rim. The device has an anchoring mechanism whereby the deployed valve apparatus is held in the desired place by anchoring to the inter-atrial septum. Prosthetic valve is deployed by first pulling the introducer sheath back to the left atrium and then releasing the anchoring device in the right atrium.

Description of the diagrams

FIG. 1. Side view of the valve, the stent/ring/base and the anchoring plate

FIG. 2. View from above (atrial side)

FIG. 3. View from below (ventricular side)

FIG. 4. Cross sectional view

FIG. 5 Cross-sectional view with the valve apparatus housed within the delivery sheath

FIG. 6. View of the valve apparatus at deployment

FIG. 7. Side profile of the valve apparatus and the anchor

FIG. 8. Set up upon valve deployment (total) and anchoring

Detailed description of the invention

The present invention includes methods and devices for implanting a heart valve percutaneously and transluminally. The artificial heart valves of the invention, which are capable of exhibiting a variable diameter between a compressed or collapsed position and an expanded position, comprise (1) a super-elastic but relatively rigid stent member and (2) a mobile valve means (3) an anchoring device to firmly fix the valve in the desired position and attached to the inter-atrial septum. The stent member is self-expanding partially and has a first cylindrical shape in its compressed or collapsed configuration and a second, larger cylindrical/ring shape in its expanded configuration. The flexible valve means comprises a generally arcuate center portion and, preferably, a peripheral upstanding cuff portion attached to the valve ring at the hinge points. The stent structure and the two leaflets of the valve apparatus are constructed as a single unit with the two leaflets being mobile at a hinge point or an equivalent structure to the stent component made of woven super-elastic malleable metal material. The leaflets may be made up of totally metal structures or totally biological material or a combination thereof. The anchoring plate is made of woven super-elastic metal wire and attached to valve base via a strong wire/string mechanism.

The whole structure is collapsible to fit into the lumen of the delivery sheath/catheter prior to deployment. It can be recaptured into the sheath in a similar manner upon deployment if the deployment is unsuccessful.

The valve leaflets are two in number – one (the outer most member) is slightly longer than the other (the innermost member). Thus once deployed it may facilitate blood flow only in one direction from the atrium to the ventricle in the left heart.

The stent member of the valve is to fit circumferentially to the native valve annulus (extending around its perimeter) and securing of the same is ensured by hooks or barbs constructed in the outer aspect of the base of the stent structure to fit into the cardiac tissue over which it is expected to be fixed and rested.

The valve apparatus is anchored in place by an anchoring device (preferably an anchoring plate) to the inter-atrial septum, the device or plate placed in the right atrial side and attached to the valve base via a multiple of strong wires or strings.

The technique of valve implantation.

1. Sizing of the valve and the annulus is done first with the help of a compliant balloon and with transthoracic and transesophageal echocardiography.

2. Once valve and annulus sizing is done, an appropriately / approximately sized valve apparatus that may expand to fit the size of the mitral annulus is selected. The valve apparatus is collapsed and stored within the delivery catheter for delivery for the purpose of deployment.

3. Right side of the heart is accessed via the right or left femoral vein and an appropriately sized sheath is inserted. A long catheter is advanced along a long j-tipped wire to the right atrium and septal puncture is performed in the conventional manner using the conventional equipment. The wire and then the catheter are advanced across the septal puncture site, left atrium and the native mitral valve to the left ventricle. Thus access is secured trans-septally and across the mitral valve to the left ventricle.

4. Left or right femoral arterial access is secured upon puncture and a sheath is inserted. A long catheter/ snare is advanced along the arterial system to the left ventricle across the aortic valve retrogradely and the pre-advanced wire tip placed in the left ventricle is captured and re-surfaced along the arterial system into the extracorporeal aspect and stabilized (this step may not be necessary if secure placement of the wire is established in the left ventricle for the valve device to be advanced for deployment).

5. Thus one end of the guide wire now rests outside of the body near the venous access site and the other end rests secured outside of the body in the arterial side. Thus the two ends of the wire that traverses the venous side, right atrium, left atrium, left ventricle and the arterial side rest out side of the body.

6. The large bore (larger than or of the size of 8F diameter) guiding catheter (delivery sheath) is now advanced over the wire along the venous side then trans septally and across the mitral valve to place its tip in the left ventricle.

7. Once the distal edge of the sheath is in the left ventricle its central core dilator (more rigid cathter) is removed and the system flushed with sterile saline mixed with heparin once ensured that the system is free of air or gaseous material.

8. Then the collapsed valve and anchor containing catheter is fed over the wire and advanced along the venous system, right atrium, then trans-septally and across the mitral valve to the level of the tip of the sheath previously placed and secured in the left ventricle.

9. Then the valve component is advanced and released in the ventricular cavity (upon which it assumes its final configuration of a rim base and two leaflets) but still attached to the anchoring device housed in the sheath via strings/wires which is connected via a releasing mechanism to a rigid wire which runs across the length of the catheter to outside of the body (proximal end of the delivery sheath) where it is attached to a handle. Then the whole apparatus is retracted so that valve apparatus is pulled firmly to rest in the desired final location over the native valve apparatus. Then the sheath and the anchoring device still housed within it is retracted to the right atrium and the anchoring device/plate is advanced and released to rest on the inter-atrial septum. Now the valve apparatus remain firmly in place anchored to the inter atrial septum by strong strings/wires. Then the anchoring device/plate is released by a mechanism that involves the handle placed in the proximal end of the delivery sheath, which is outside of the body. The deployment process is guided by fluoroscopy, transthoracic and transesophageal echocardiography.

10. Once the valve is securely and firmly deployed the catheter and the delivery sheath are removed.

PTO/SB/01 (08-03)
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☑ Declaration Submitted With Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	
First Named Inventor	SATYAJIT R JAYASINGHE
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SATYAJIT ROHAN JAYASINGHE - 310 EAST 24th STREET APT #2L NEW YORK NY 10010
CITIZEN OF SRI LANKA.

(Title of the Invention)

the specification of which PROSTHETIC MITRAL HEART VALVE AND ANCHORING DEVICE FOR PER CUTANEOUS DEPLOYMENT

☑ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) ☐ as United States Application Number or PCT International Application Number ☐ and was amended on (MM/DD/YYYY) ☐ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? Yes	No
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ Customer Number: _____ OR ☐ Correspondence address below

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Address: 310 EAST 24TH STREET APT #2L NEW YORK NY 10010

City	State	ZIP
NEW YORK	NY	10010

Country	Telephone	Fax
USA	917 806 6334	212 420 2046

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
SATYAJIT ROHAN	JAYASINGHE

Inventor's Signature: _____ Date: 3-4-4

Residence: City	State	Country	Citizenship
NEW YORK	NY	USA	SRI LANKA

Mailing Address: 310 EAST 24TH STREET APT #2L NEW YORK

City	State	ZIP	Country
NEW YORK	NY	10010	USA

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature: _____ Date: _____

Residence: City	State	Country	Citizenship

Mailing Address: _____

City	State	ZIP	Country

☐ Additional Inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

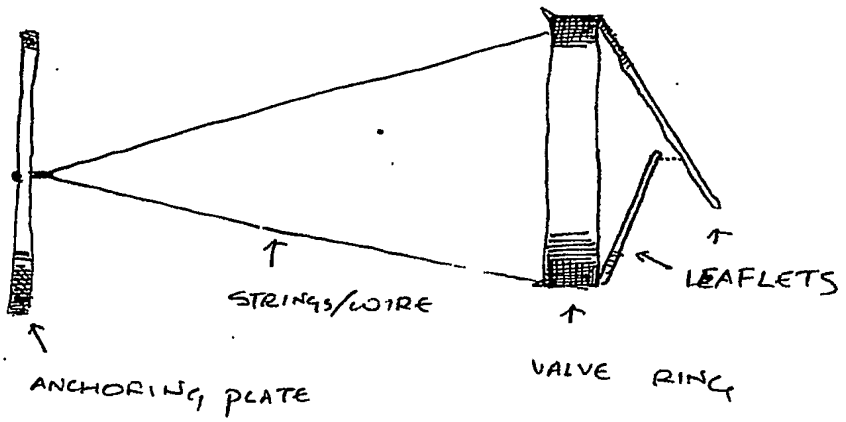

FIGURE : 1

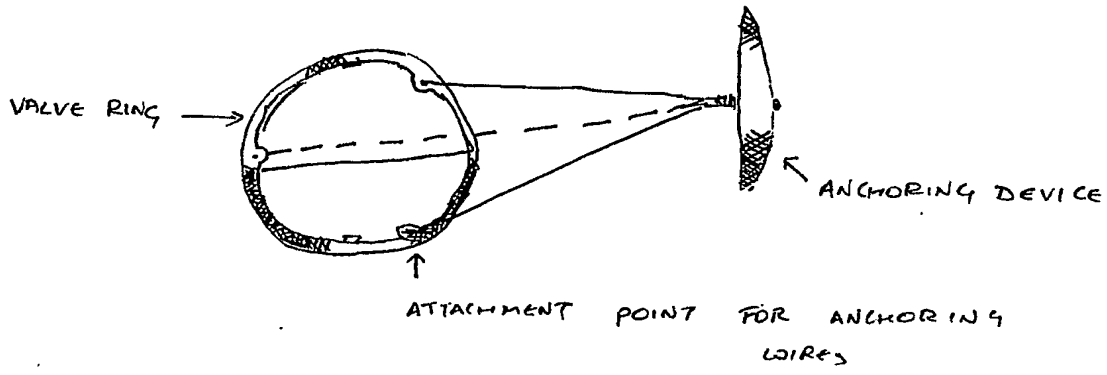

FIGURE : 2

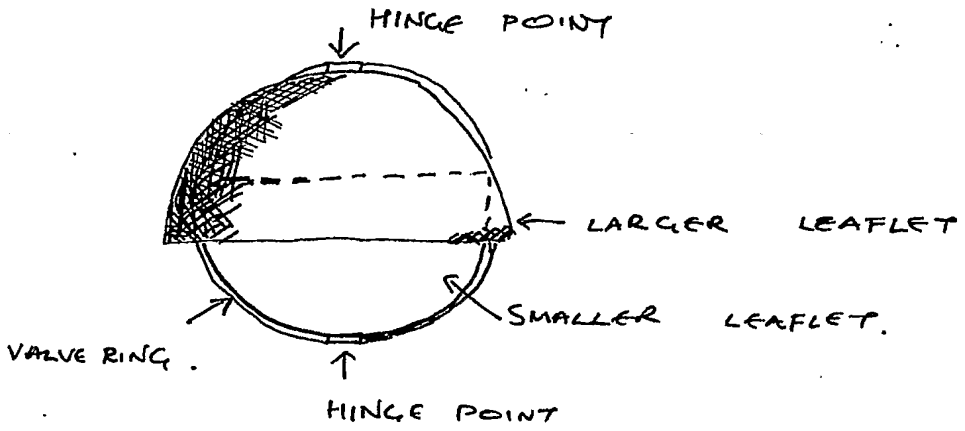

FIGURE 3

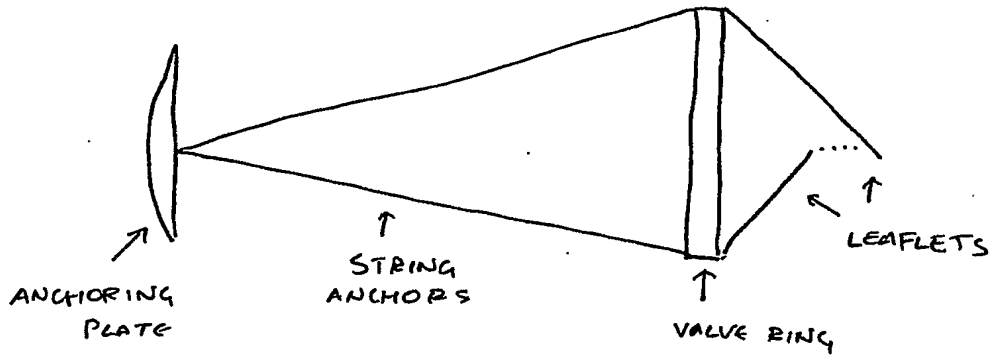

FIGURE 4

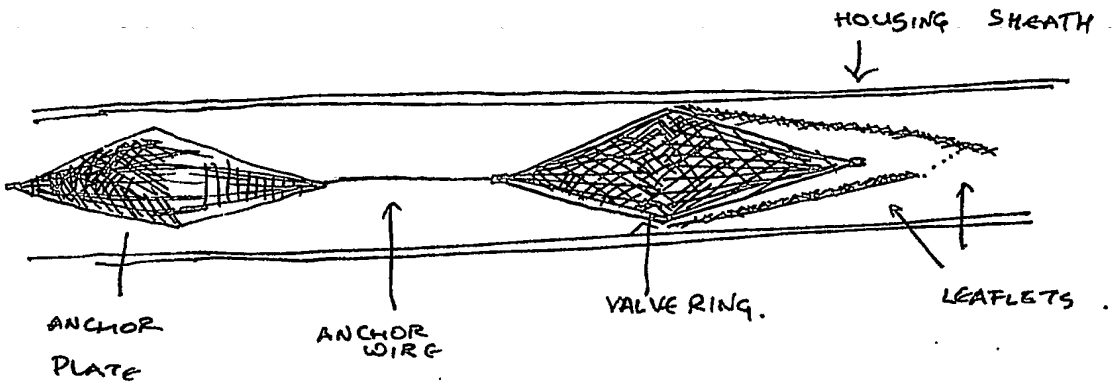

FIGURE 5

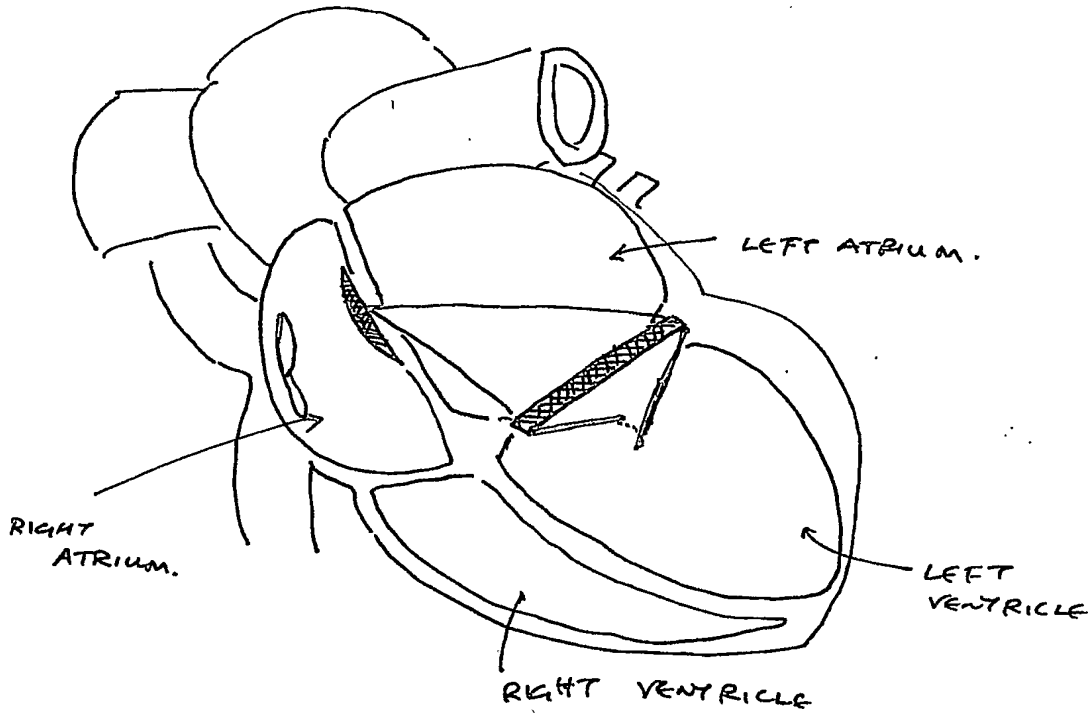

FIGURE 6.

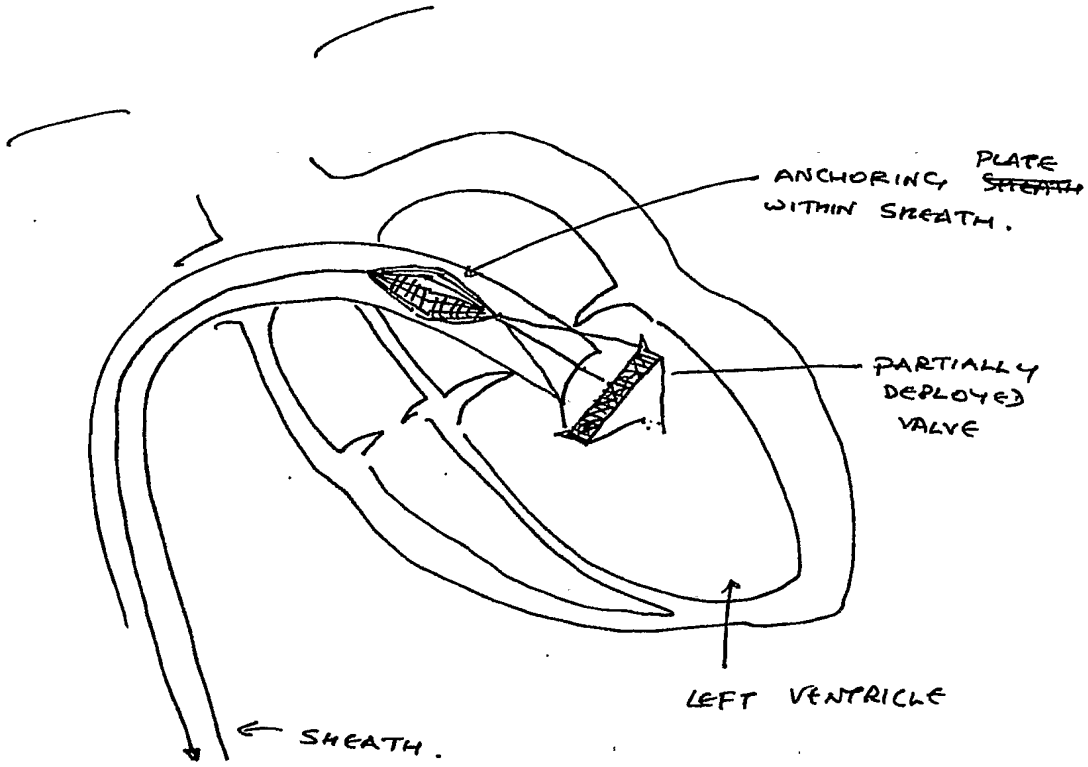

FIGURE 7.

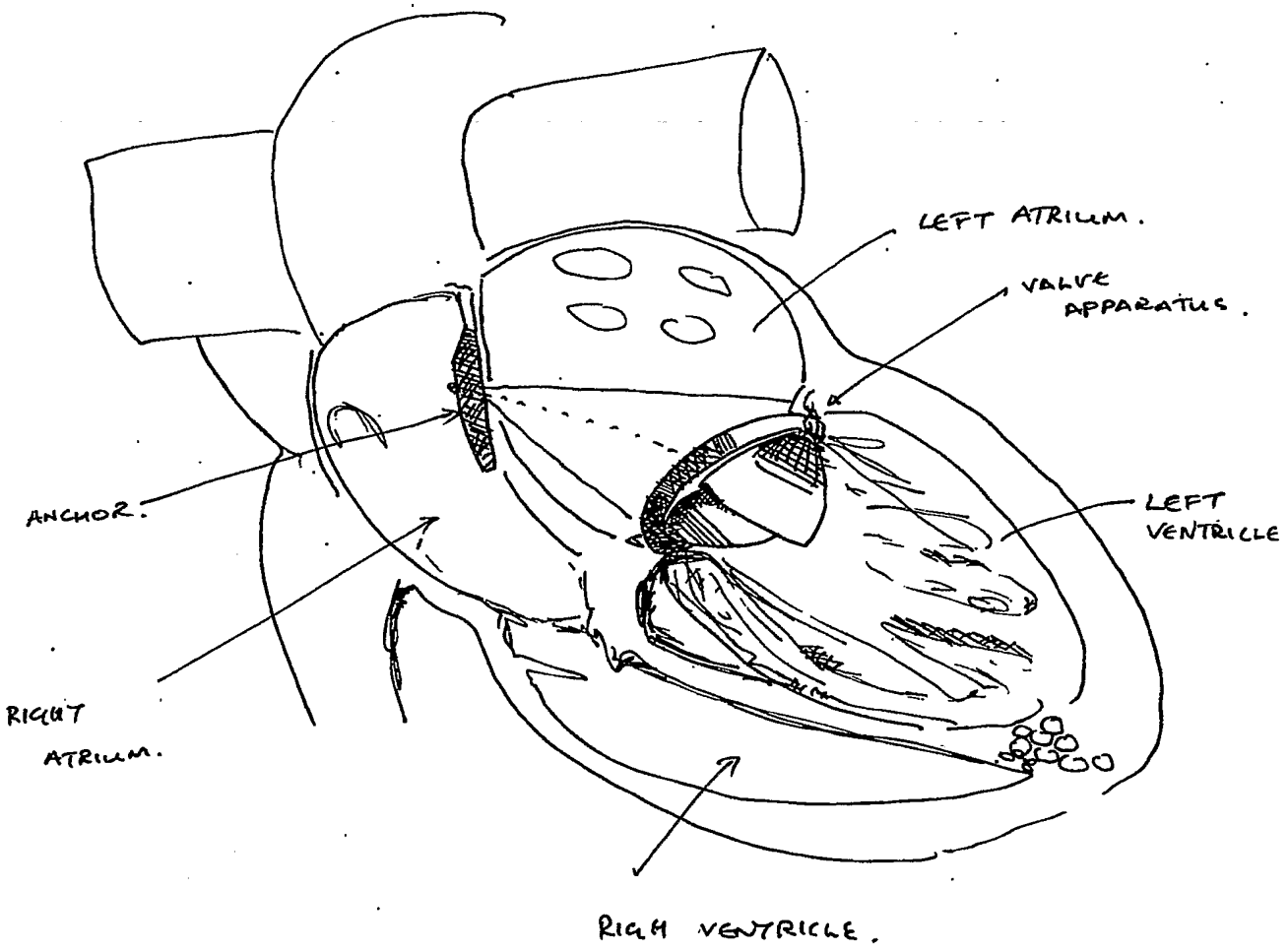

FIGURE 3